



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MJ

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/501,714 | 02/10/00 | AU-YOUNG | J PF-0309-3 DI |

HM22/0621
Incyte Pharmaceuticals Inc
Patent Department
3174 Porter Drive
Palo Alto CA 94304

EXAMINER

SLOBODYANSKY, E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED:

6
06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/501,714

Applicant(s)
Au-Young et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Feb 10, 2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 43-65 is/are pending in the application.

Of the above, claim(s) 43, 44, 50, 51, and 57-64 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 45, 47-49, and 52-56 is/are rejected.

☒ Claim(s) 46 and 65 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

This application is a divisional of 09/388,993, now US Patent 6,043,222.

The preliminary amendment filed concurrently with the application amending the specification to correct typographical errors, canceling claims 1-42 and adding claims 43-65 has been entered.

Claims 43-65 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 43, 44 and 57, drawn to a polypeptide and a pharmaceutical composition comprising thereof, classified in class 514, subclass 12.
- II. Claims 45-49, 52-56 and 65, drawn to a DNA encoding a polypeptide, a cell transformed with said DNA, a recombinant method of making a polypeptide and a method of use of said DNA, classified in class 435, subclass 6.
- III. Claim 50, drawn to a transgenic animal, classified in class 800, subclass 2.
- IV. Claim 51, drawn to an antibody against a polypeptide, classified in class 530, subclass 387.1.

Art Unit: 1652

- V. Claims 58 and 59, drawn to a pharmaceutical composition comprising an agonist and a method of use thereof, classified in class 514, subclass 789.
- VI. Claims 60-64, drawn to a pharmaceutical composition comprising an antagonist and methods of use thereof, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and IV-VI are patentably distinct because a DNA, a protein, an antibody, an agonist and an antagonist are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule of inventions II is not limited in use to the production of a polypeptide of invention I and can be used as a hybridization probe, and a polypeptide of invention I can be obtained by a materially different method such as by the biochemical purification. An animal of invention III and inventions I, II and IV-VI are patentably distinct because an animal is a live complex organism comprising many compounds while inventions I, II and IV-VI are drawn to specific chemical compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into

Art Unit: 1652

different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

During a conversation with Dr. Diana Hamlet-Cox on May 15, 2000 a provisional election was made with traverse to prosecute the invention of Group II, claims 45-49, 52-56 and 65.

Claims 45-49, 52-56 and 65 are examined.

Claim Objections

Claims 45 and 49 are objected to because of the following: Claims 43 and 49 depend from non-elected claim 43. However, claims 45 and 49 were treated as if they were properly written, i.e. included all limitations of claim 43, in the interests of compact prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, with dependent claims 47-48, claim 49 and claim 52, with dependent claims 53-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject

Art Unit: 1652

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NOS: 2 or 4; or DNA having the limitations of encoding a protein having the SEQ ID NOS: 1 or 3; or any DNA which is 90% identical to SEQ ID Nos:2 or 4; or encodes a protein that is 90% identical to SEQ ID Nos:1 or 3.

The specification does not contain any disclosure of the function of all DNA sequences that are 90% identical to SEQ ID NOS:2 or 4. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Art Unit: 1652

Claims 45, with dependent claims 47-48, claim 49 and claim 52, with dependent claims 53-56, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding SEQ ID Nos:1 or 3, does not reasonably provide enablement for a 90% identical DNA or a DNA encoding proteins 90% identical to SEQ ID NOs 1 or 3 that do not have an enzymatic activity.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 45, 49 and 52 are drawn to a DNA encoding both a polypeptide having an enzymatic activity and an inactive variant thereof. The specification does not teach how to use said inactive variant. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. Therefore, one skilled in the art would require guidance as to how to use a DNA with 90% identity or a DNA encoding a polypeptide with 90% identity. Without such guidance, the experimentation left to those skilled in the art is undue.

Art Unit: 1652

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-49, 52 and 53 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 5,922,567 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a DNA encoding SEQ ID NO:1 including the specific DNA of SEQ ID NO:2, a vector and a host cell comprising thereof and a method of use thereof.

Art Unit: 1652

Claims 45-49, 52 and 53 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 6,001,598 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

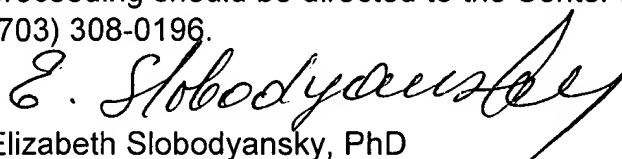
The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a DNA encoding SEQ ID NO:3 including the specific DNA of SEQ ID NO:4, a vector and a host cell comprising thereof and a method of use thereof.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert a. Wax, can be reached at (703) 308-4216. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD